

Immunization Registries and the Law: Q&A with DHS Privacy Officer

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*California Department of Health Services,
Immunization Branch,
Statewide Immunization Information System
in collaboration with the
Medi-Cal Managed Care Division*

*Presented by California Department of Health Services,
Immunization Branch, Statewide Immunization Information System In collaboration with the
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Presentation Summary

- Disclosure & Re-disclosure
- Restrictions on Use by Health Care (and Non-Health Care) Entities
- Rights of Parents and Children
- Obligations of Providers and Others
- Q&A (based on advance-submitted questions)

Disclosure

The HIPAA Privacy Rule allows covered health plans and providers to disclose information to the Immunization Registry:

- HIPAA does not pre-empt state laws which provide for the conduct of public health surveillance or intervention.
- §120440 of the H&S Code, Immunization Information Systems, is such a state law.

Disclosure (Cont'd)

HIPAA also permits health plans and providers to:

- Disclose health information to a public health authority authorized by law to:
- Collect or receive the information for the purpose of preventing disease and conducting public health surveillance and interventions.

Disclosure (Cont'd)

Public health officers and DHS Immunization Branch are public health authorities authorized by §120440 to:

- Collect and receive immunization information, and
- Operate registries in order to prevent disease and conduct public health interventions.

Re-disclosure

Re-disclosure of information by a public health authority exempt from HIPAA is controlled by State statute.

§120440 allows local health departments and DHS to disclose reported immunization information to each other.

Re-disclosure (Cont'd)

Upon a request for information pertaining to a specific person:

- To health care providers taking care of the patient.
- Except for address and telephone number-- to schools, child care facilities, county welfare departments, and family child care homes to which the patient is being admitted or is in attendance, and to WIC service providers, health plans, and county welfare departments.

Restrictions on Use by Health Care Entities

- Once immunization information is re-disclosed by the registry, confidentiality of the data must be protected in the same manner as other identifiable medical information by health care providers, local health depts, DHS, and health plans.
- This means that if the provider, health plan or local health department is covered by HIPAA, then HIPAA rules on safeguards and uses and disclosures apply--except...

Restrictions on Use by Health Care Entities (Cont'd)

Except...that the uses of immunization registry information are restricted under the statute, to:

- Provide IZ services to the client, including reminder notifications
- Facilitate third party payment
- Compile and disseminate de-identified IZ status information by groups of patients
- (For health care plans only) facilitate payments to providers and to assess the IZ status of their clients, AND
- (For health care providers only) as authorized by CA Confidentiality of Medical Information Act

Restrictions on Use By Non-Health Care Entities

H&S Code §120440 specifies uses for IZ information disclosed by registries to non-health care entities, (which may use the information as explained previously for health care entities) and as follows:

- **Schools, child care facilities, family child care homes, and county welfare departments:**
 - To carry out attendance or participation for benefits responsibilities;
- **WIC service providers**
 - To perform IZ status assessments and refer clients to providers when necessary.

Restrictions on Use By Non-Health Care Entities (Cont'd)

- Non-health care entities must also maintain the confidentiality of the information obtained from the registries in the same manner as other client and pupil information that they possess.
- All entities receiving registry information are subject to civil action and criminal penalties for wrongful disclosure of information obtained from the registry.

Rights of Parents and Children

Similar to the HIPAA Privacy Rule, H&S Code §120440 gives patients or their parents or guardians the right to:

- Refuse to permit disclosures to the registries at any time.
- Examine any IZ information shared with the registry and to correct errors in it.
- Refuse to receive IZ reminder notifications at any time.
- Request an accounting of disclosures of persons or agencies with whom the registry has shared information.

Obligations of Providers and Others

Any health care provider, health plan, or any other agency possessing IZ information must notify the parent or guardian of the intention to share the information with the registry.

- If parent or guardian opts out of the immunization registry record sharing, then the health care provider, health plan or other agency may not share this information with the registry.

Obligations of Providers and Others (Cont'd)

- Local health department and DHS must provide names and addresses of persons or agencies who have received IZ registry information, when a parent requests it, and must stop sharing information in its possession after the date of the receipt of the request.
- Local health department and DHS must correct an error in the registry information, upon notification by a parent or guardian, or place a disagreement in the file.

Questions from the Field



Questions on Notification

- 1) *May the regional registries notify parents by mail?*
- 2) *May health plans notify parents by mail?*
- 3) *For a mailed notification, what are the requirements for*
 - *font size;*
 - *reading level;*
 - *availability in languages other than English;*
 - *other formatting or content requirements?*

More Questions on Notification

- 4) *When notifying by mail, what is considered a “reasonable time” to wait for a response?*
- 5) *When notifying by mail, what are considered “reasonable means” to decline:*
 - *mail, regular or special;*
 - *telephone, pay or toll-free;*
 - *Internet;*
 - *other?*
- 6) *What is required to verify parental refusal to share?*
 - *signature;*
 - *other?*

Question on Disclosure

- 7) *If a registry is operating as a covered entity instead of an exempt entity, does it:*
- *need its providers to obtain a signed disclosure from parents?*
 - *affect the sharing of records with other authorized partners such as*
 - *Providers;*
 - *Health plans;*
 - *Schools;*
 - *Childcare;*
 - *WIC?*

Questions on HIPAA Rules

- 8) *The public health system is exempt under HIPAA for immunization registry-related activities. How does HIPAA apply to registry activities performed by entities that are legally authorized to use the registry, such as*
- *health care providers, private or public;*
 - *health plans?*
- 9) *How does each party's status as either a public health-exempt or a covered entity affect written agreements between providers and registries?*

Question on HIPAA Rules

10) Are there any HIPAA or other privacy implications raised by the extraction or transfer of public or private electronic billing data into the immunization registries?

Question on Proposed Change to H&S Code

11) It has been proposed to add other childhood public health information, including TB skin testing, childhood lead testing, and newborn genetic screening results to the registry for access by physicians and the public health system. Would these additions alter the system's exemption from HIPAA requirements? Could these results be added to the registry without a change in the Health and Safety Code?

Questions on Parental Consent and Patient Privacy

- 12) If one parent consents and the other declines participation, are their child's immunization records allowed in the registry?*
- 13) Do providers need to indicate registry participation in their patient privacy statements in addition to a registry disclosure form? If so, does a provider have to reissue a revised privacy statement to all patients? Is it sufficient to post a revised privacy statement in the office?*

Question on Patient Privacy and HIPAA Compliance

14) Under HIPAA, are reminder postcards for immunizations allowed if specific vaccine names are absent (e.g., “Our records show that Johnny is due for shots”, not “Our records show that Johnny is due for a Hepatitis B shot”)?

Questions Data Exchange and Protection

15) How should protected patient health information provided by a registry for a health plan HEDIS audit be retained or stored?

- *For how long?*
- *In what format (hard copy or electronic)?*

16) One MCMC plan wants to create its multifunctional electronic version of the CHDP PM-160 billing form to avoid separate key entry of immunization registry data. Is this acceptable?

Questions on Data Sharing and Agreements

17) May registries share their data with health plans for

- *HEDIS assessments;*
- *Other QA efforts;*
- *Other reasons?*

18) Does a health plan that operates in multiple registry regions need to arrange an MOU with each region? If so, do all MOUs need to be identically worded?

For More Information

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- State Registry
http://www.leginfo.ca.gov/pub/99-00/bill/asm/ab_1701-1750/ab_1748_bill_20000924_chaptered.html